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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Complete if Known Application No. 10/789,471 Substitute for Form 1449/A/PTO Filing Date 02/27/2004 INFORMATION DISCLOSURE First Named Inventor D'Amato et al. STATEMENT BY APPLICANT Group Art Unit 1609 (use as many sheets as necessary) **Examiner Name** Brooks, Kristie L. Sheet **Attorney Docket Number** of 05213-3001 (13663-105082) 42 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite T٥ item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No.1 publisher, city and/or country where published 53 Author: Title: News Article: Hoffman-La Roche Signs \$70 Million Deal with Millenium on Genomics Technology Publ-/K.B./ Genetic Engineering News Vol/Iss: Pages: Date: 4/15/1994 Title: News Article: Advanced Drug Delivery Systems Peak Interest of Pharmaceutical & Author: **Biotech Firms** Publ: Genetic Engineering News Vol/lss: Pages: 4/15/1994 Title: News Article: Nasal Spray for Treating Bleeding Disorders Author: Publ: Genetic Engineering News Vol/Iss: Pages: Author: Title: 2-Methoxyestradiol - An Orally Active Endogenous Inhibitor of Angiogenesis Publ: EntreMed Website Article Vol/Iss: Pages: 1-10 Date: 7/11/2000 Title: Peripheral Ulcerative Keratitis (Marginal Keratolysis; Peripheral Rheumatoid Author: Ulceration) (Abstract only-Applicants do not have complete copy) Publ: Merck Manual of Diagnosis and Therapy Vol/Iss: Sec. 8 Pages: Chapter 8 & 96 Date: Author: AGUAYO et al. Title: Angiogenesis in Acute and Chronic Leukemias and Myelodysplastic Syndrome Publ: Blood Vol/Iss: 96 (6) Pages: 2240-2245 Date: 09/15/2000 Author: AKOVA et al. Title: Optic Disk Neovascularization in a Patient with Cytomegalovirus Retinitis

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1				Filing Date	02/27/2004
	I	NFC	PRMATION DISCLOSURE	First Named Inventor	D'Amato et al.
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<u> </u>			(use as many sheets as necessary)	Examiner Name	Brooks, Kristie L.
	Sheet		9 of 42	Attorney Docket Number	05213-3001 (13663-105082)
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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Complete if Known Application No. 10/789,471 Substitute for Form 1449/A/PTO Filing Date 02/27/2004 INFORMATION DISCLOSURE First Named Inventor D'Amato et al. STATEMENT BY APPLICANT Group Art Unit 1609 (use as many sheets as necessary) **Examiner Name** Brooks, Kristie L. Attorney Docket Number 05213-3001 (13663-105082) Sheet of 10 42 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No.1 publisher, city and/or country where published Title: Mechanisms of cell death and survival in multiple myeloma (MM): Therapeutic Author: CHAUHAN et al. implications /K.B./ Publ: Apoptosis Vol/Iss: 8 (4) Pages: 337-343 Date: Title: Superoxide-dependent and -independent mitochondrial signaling during apoptosis in Author: CHAUHAN et al. multiple myeloma cells Publ: Oncogene Vol/Iss: 22 Pages: 6296-6300 Date: 01/2003 Author: CHAUHAN et al. Title: 2-Methoxyestradiol overcomes drug resistance in multiple myeloma cells Publ: Blood Vol/Iss: 100 (6) Pages: 2187-2194 09/15/2002 Date: Title: A Radical Approach to Treatment Author: CLEVELAND et al. Publ: Nature Pages: 309-311 Vol/iss: 407 09/21/2000 Date: Title: Apoptosis Author: CUMMINGS et al. The American Journal of Surgical Pathology Pages: 88-101 Title: Angiogenesis in Comeal Disease: Histopathologic Evaluation of 254 Human Comeal Author: CURSIEFEN et al. **Buttons with Neovascularization** Pubi: Comea Vol/Iss: 17 (6) Pages: 611-613 Date: Author: CUSHMAN et al. Title: Synthesis, Antitubulin and Antimitotic Activity, and Cytotoxicity of Analogs of

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2-Methoxyestradiol, an Endogenous Mammalian Metabolite of Estradiol that Inhibits

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	S	TAT	TEMENT BY APPLICANT	Group Art Unit	1609
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			OTHER PRIOR ART - NON PAT	ENT LITERATURE DOCU	MENTS
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Substitute for Form 1449/A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 14 of 42 Attorney Docket Number 05213-3001 (13653-105082) OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Examiner Name Brooks, Kristle L. Attorney Docket Number 05213-3001 (13653-105082) OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(3), volume-issue number(10), publisher, oily and or country where publisher Individual Author: EDSALL et al. Title: Effects of Altering the Electronics of 2-Methoxyestradiol on Cell Proliferation, on Cytotoxicity in Human Cancer Cell Cultures, and on Tubulin Polymerization Countries of Training Thiadiazole, Thiazoline, ab/M Thiazolidinone Moicties Vollas: 47 Pages: 5126-5139 Date: 01/2004 117 Author: EL-TOMBARY. Title: Symbasis, Uterotropic, And Antiuterrophic Activities of Some Estradiol Derivatives Containing Thiadiazole, Thiazoline, ab/M Thiazolidinone Moicties Vollas: 330 (9-10) Pages: 295-302 Date: 1997 118 Author: FAJARDO et al. Title: Effects of Genistein and 2-Methoxyestradiol on Marix Matalloproteinases and their Inhibitors Sceneted by Ehrlich Ascites Tumor Cells Author: FARMER et al. Title: Retinal Vasculitis Associated with Autonatiobelies to Sjogren's Syndrome A Antigen (Abstract only-Applicants do not have complete copy) Vollas: 20 Pages: 814-821 Date: 12/01/1385 120 Author: FEHER et al. Title: Multiple Flexible Alignment with SEAL: A Study of Molecules Acting on the Cochecime Binding Site Journal of Chemical Information and Computer Sciences Vollas: 20 Pages: 495-502 Date: 01/01/2000 121 Author: FOTSIS et al. Title: Inhibition of angiogenesis: treatment options for patients with metastatic prostate cancer lavesticational New Druss Vollas: 20 Pages: 183-194 Date: 03/1/194				Complete if Known						
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Complete if Known 10/789,471 Application No. Substitute for Form 1449/A/PTO Filing Date 02/27/2004 INFORMATION DISCLOSURE First Named Inventor D'Amato et al. STATEMENT BY APPLICANT Group Art Unit 1609 (use as many sheets as necessary) **Examiner Name** Brooks, Kristie L. Sheet Attorney Docket Number 05213-3001 (13663-105082) 42 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No. publisher, city and/or country where published 130 Author: HAJJAR et al. Title: New Concepts in Fibrinolysis and Angiogenesis (Abstract only-Applicants do not /K.B./ have complete copy) Publ: Current Atherosclerosis Reports Vol/lss: 2 (5) Pages: 417-421 09/01/2000 Author: HALDAR et al. Title: Bc12 is the Guardian of Microtubule Integrity Publ: Cancer Research Vol/Iss: 57 Pages: 229-233 Date: 01/15/97 Author: HAMANAKA et al. Title: Retinal Ischemia and Angle Neovascularization in Proliferative Diabetic Retinopathy (Abstract only-Applicants do not have complete copy) American Journal of Ophthalmology Vol/Iss: 132 (5) Pages: 648-658 11/01/2001 Title: Interactions of 2-Methoxyestradiol, an Endogenous Mammalian Metabolite, with 133 Author: HAMEL et al. Unpolymerized Tubulin and with Tubulin Polymers Publ: Biochemistry Vol/lss: 35 (4) Pages: 1304-1310 Date: 1996 134 Author: HAMMERS et al. Title: Introduction of a novel proliferation assay for pharmacological studies allowing the combination of BrdU detection and phenotyping

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U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Complete if Known Application No. 10/789,471 Substitute for Form 1449/A/PTO Filing Date 02/27/2004 INFORMATION DISCLOSURE First Named Inventor D'Amato et al. STATEMENT BY APPLICANT Group Art Unit 1609 (use as many sheets as necessary) **Examiner Name** Brooks, Kristie L. Sheet Attorney Docket Number of 05213-3001 (13663-105082) 42 17 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No.1 publisher, city and/or country where published 137 Title: A Versatile Synthesis of 2-Methoxyestradiol, an Endogenous Metabolite of Estradiol Author: HE et al. which Inhibits Tubulin Polymerization by Binding to the Colchicine Biding Site /K.B./ Publ: Bioorganic & Medicinal Chemistry Letters Vol/Iss: 4 (14) Pages: 1724-1728 1994 Date: Author: HE et al. Title: Novel Cytokine Release Inhibitors. Part II: Steroids 138 Publ: Bioorganic & Medicinal Chemistry Letters Vol/lss: 8 Pages: 2825-2828 Date: Title: Synthesis and Biological Activity of the Superestrogen (E)-17-Oximino-3-O-139 Author: HEJAZ et al. sulfamoyl-1,3,5(10)-estratriene: X-ray Crystal Structure of (E)-17-Oximino-3hydroxy-1,3,5(10)-estratriene Journal of Medicinal Chemistry Vol/lss: 42 (16) Pages: 3188-3192 Date: 1999 Author: HILL et al. Title: Pathogenesis of Pterygium (Abstract only-Applicants do not have complete copy) Publ: Eye Vol/Iss: 3 (Pt 2) Pages: 218-226 Date: 01/01/1990 141 Title: Estrogens and Anti-Estrogens: Key Mediators of Prostate Carcinogenesis and New Author: HO, Shuk-Mei Therapeutic Candidates Journal of Cellular Biochemistry Pages: 491-503 Vol/iss: 91 1/1/2004 Title: Interleukin-8 Stimulates Angiogenesis in Rats 142 Author: HU et al. Publ: Inflammation Vol/Iss: 17 (2) Pages: 135-143 04/01/1993 Title: Neomycin Inhibits Angiogenin-induced Angiogenesis (Abstract only-Applicants do 143 Author: HU, G. /K.B not have complete copy)

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Complete if Known Application No. 10/789,471 Substitute for Form 1449/A/PTO Filing Date 02/27/2004 INFORMATION DISCLOSURE First Named Inventor D'Amato et al. STATEMENT BY APPLICANT Group Art Unit 1609 (use as many sheets as necessary) **Examiner Name** Brooks, Kristie L. Sheet of 42 Attorney Docket Number 05213-3001 (13663-105082) 18 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials publisher, city and/or country where published Title: Superoxide Dismutase as a Target for the Selective Killing of Cancer Cells (Abstract 144 Author: HUANG et al. /K.B./ only-Applicants do not have complete copy) Publ: Nature Vol/Iss: 407 (6802) Pages: 390-395 9/21/2000 Title: 2-Methoxyestradiol and Analogs as Novel Antiproliferative Agents: Analysis of Author: HUGHES et al. Three Dimensional Quantitative Structure-Activity Relationships for DNA Synthesis Publ: Inhibition and Estrogen Receptor Binding Molecular Pharmacology Vol/lss: 61 (5) Pages: 1053-1069 Date: Author: HUOBER et al. Title: Oral Administration of an Estrogen Metabolite-Induced Potentiation of Radiation Antitumor Effects in Presence of Wild-Type p53 in Non-Small-Cell Lung Cancer International Journal of Radiation Oncology. Biology, Physics Vol/lss: 48 (4) Pages: 1127-1137 Date: Author: IKEGAWA et al. Title: Immunoaffinity Extraction for Liquid Chromatographic Determination of Equilin and Its Metabolites in Plasma (Abstract only-Applicants do not have complete copy) Publ: Biomed, Chromatogr. Vol/Iss: 10 (2) Pages: 73-77 1996 Date: Title: Molecular Mechanism of Diclofenac-Induced Apoptosis of Promyelocytic Leukemia: Author: INOUE et al. Dependency on Reactive Oxygen Species, AKT, BID, Cytochrome c, and Caspase Pathway Free Radical Biology & Medicine Vol/lss: 37 (8) Pages: 1290-1299 Date: 1/1/2004 Author: IRESON et al. Title: Pharmacokinetics and efficacy of 2-methoxyestradiol and 2-methoxyestradiol- bissulphamate in vivo in rodents British Journal of Cancer Vol/Iss: 90 Pages: 932-937 1/1/2004 150 Title: The Codependence of Angiogenesis and Chronic Inflammation Author: JACKSON et al. /K.B./ Publ:

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Examiner	W. S. D. L.	Date		
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¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language translation is attached.

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			Filing Date	05/19/2005
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	STAT	TEMENT BY APPLICANT	Group Art Unit	1621
		(use as many sheets as necessary)	Examiner Name	Brooks, Kristie L.
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				Filing Date	05/19/2005
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	S	TAT	TEMENT BY APPLICANT	Group Art Unit	1621
			(use as many sheets as necessary)	Examiner Name	Brooks, Kristie L.
	Sheet		28 of 42	Attorney Docket Number	05213-0926 (13663-105080)
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}				Filing Date	02/27/2004
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	S	TAT	TEMENT BY APPLICANT	Group Art Unit	1609
			(use as many sheets as necessary)	Examiner Name	Brooks, Kristie L.
	Sheet		29 of 42	Attorney Docket Number	05213-3001 (13663-105082)
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				Filing Date	02/27/2004
	11	NFO	RMATION DISCLOSURE	First Named Inventor	D'Amato et al.
	S	TAT	TEMENT BY APPLICANT	Group Art Unit	1609
L.			(use as many sheets as necessary)	Examiner Name	Brooks, Kristie L.
	Sheet		30 of 42	Attorney Docket Number	05213-3001 (13663-105082)
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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Complete if Known Application No. 10/789,471 Substitute for Form 1449/A/PTO 02/27/2004 Filing Date INFORMATION DISCLOSURE First Named Inventor D'Amato et al. STATEMENT BY APPLICANT Group Art Unit 1609 (use as many sheets as necessary) **Examiner Name** Brooks, Kristie L. Attorney Docket Number 05213-3001 (13663-105082) Sheet of 31 42 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Citc item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No.1 publisher, city and/or country where published Title: Synthesis and antimitotic activity of novel 2-methoxyestradiol analogs 235 Author: RAO et al. /K.B./ Publ: Steroids Vol/Iss: 67 Pages: 1079-1089 01/2002 Date: Title: A new, practical synthesis of 2-methoxyestradiols 236 Author: RAO et al. Publ: Steroids Pages: 1065-1070 Vol/Iss: 67 Date: Title: Inhibition of MCF-7 breast cancer cell proliferation and in vivo steroid sulphatase Author: RAOBAIKADY et al. activity by 2-methoxyestradiol-bis-sulphamate The Journal of Steroid Biochemistry & Molecular Biology Pages: 351-358 Vol/Iss: 84 01/2003 Date: Title: Ocular Complications of Adult Rheumatoid Arthritis (Abstract only-Applicants do 238 Author: REDDY et al. not have complete copy) Rheumatology International Pages: 49-52 Vol/lss: 16 (2) Date: 01/01/1996 Title: Aromatase Regulation and Breast Cancer Author: REED et al. 239 Clinical Endocrinology Vol/Iss: 54 Pages: 563-571 Title: Anti-Angiogenesis: A Multipurpose Therapeutic Tool? Author: RIBATTI et al. Publ: International Journal of Clinical & Laboratory Research Vol/Iss: 23 (3) Pages: 117-120 Date: 241 Author: RIONO et al. Title: Scleritis: A Clinicopathologic Study of 55 Cases (Abstract only-Applicants do not have complete copy) Publ: /K.B./

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Complete if Known Application No. 10/789,471 Substitute for Form 1449/A/PTO Filing Date 02/27/2004 INFORMATION DISCLOSURE **First Named Inventor** D'Amato et al. STATEMENT BY APPLICANT Group Art Unit 1609 (use as many sheets as necessary) **Examiner Name** Brooks, Kristie L. Sheet of Attorney Docket Number 05213-3001 (13663-105082) 42 32 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No. publisher, city and/or country where published Title: Safety and Pharmacokinetics of Intravitreal 2-Methoxyestradiol Implants in Normal 242 Author: ROBINSON et al. Rabbit and Pharmacodynamics in a Rat Model of Choroidal Neovascularization /K.B./ Experimental Eve Research Vol/Iss: 74 Pages: 309-317 Date: Title: Retinal Vein Occlusion (Abstract only-Applicants do not have complete copy) Author: ROBINSON et al. Publ: American Family Physician Vol/Iss: 45 (6) Pages: 2661-2666 06/01/1992 Date: Title: Identification of Small Molecular Binding Sites within Proteins Using Phage Display Author: RODI et al. Technology Combinatorial Chemistry & High Throughput Screening Pages: 553-572 Date: 01/01/2001 Title: Macular Translocation for Subfoveal Choroidal Neovascularization in Angioid Author: ROTH et al. 245

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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number Complete if Known Application No. 10/789,471 Substitute for Form 1449/A/PTO 02/27/2004 Filing Date INFORMATION DISCLOSURE First Named Inventor D'Amato et al. STATEMENT BY APPLICANT Group Art Unit 1609 (use as many sheets as necessary) **Examiner Name** Brooks, Kristie L. Sheet Attorney Docket Number 05213-3001 (13663-105082) of 42 OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the Examiner Cite item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), Initials No. publisher, city and/or country where published Title: An Optimized Synthesis of 2-Methoxyestradiol, a Naturally Occurring Human 298 Author: WANG, Z. et al. Metabolite with Anticancer Activity Publ: /K.B./ Synth.Commun. Vol/lss: 28 (23) Pages: 4431-4437 Title: Management of Mooren's Ulceration (Abstract only-Applicants do not have 299 Author: WATSON, P.G. complete copy) Publ: Eve Pages: 349-356 Vol/Iss: 11 (Pt 3) Author: WIEDEMANN, P. Title: Growth Factors in Retinal Disease: Proliferative Vitreoretinopathy, Proliferative Diabetic Retinopathy, and Retinal Degeneration (Abstract only-Applicants do not Publ: have complete copy) Survey of Ophthalmology Vol/Iss: 36 (5) Pages: 373-384 03/01/1992 Date: Title: Induction of the Estrogen Specific Mitogenic Response of MCF-7 Cells by Author: WIESE et al. Selected Analogues of Estradiol-17 p. A 3D QSAR Study Publ: Journal of Medicinal Chemistry Vol/iss: 40 Pages: 3659-3669 Date: 1997 302 Author: WOOD et al. Title: 2-MeOE2bisMATE induces caspase-despendent apoptosis in CAL51 breast cancer cells and overcomes resistance to TRAIL via cooperative activation of caspases Publ: Apoptosis Vol/Iss: 9 Pages: 323 - 332 Title: Three-Dimensional Models of Estrogen Receptor Ligand Binding Domain Author: WURTZ et al. Complexes, Based on Related Crystal Structures and Mutational and Structure-Publ: Activity Relationship Data Journal of Medicinal Chemistry Vol/lss: 41 Pages: 1803-1814 Date:

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¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent document, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language translation is attached.

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